COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.09.2004
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NOT FOR PUBLICATION

COMMISSION DECISION

of 20.09.2004

granting the marketing authorization for the medicinal

product for human use,

"Alimta - pemetrexed"

(Text with EEA relevance)

ONLY THE DUTCH TEXT IS AUTHENTIC

COMMISSION DECISION

of 20.09.2004

granting marketing authorisation for the medicinal product for human use "Alimta - pemetrexed" under Council Regulation (EEC) No 2309/93

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to the application submitted by Eli Lilly Nederland B.V., on 18 August 2003, under Article 4(1) of Regulation (EEC) No 2309/93,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 23 June 2004,

Whereas:

(1) The medicinal product "Alimta - pemetrexed" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3] as amended by Directive 2002/98/EC[4] and by Directive 2003/63/EC[5].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.
[4] OJ L 33, 8.2.2003, p. 30.
[5] OJ L 159, 27.6.2003, p. 46.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "Alimta - pemetrexed" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the numbers:

EU/1/04/290/001 Alimta-500 mg-Powder for concentrate for solution for infusion-Intravenous use-Vial (glass)-1 vial

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Eli Lilly Nederland B.V., Grootslag 1-5, 3991 RA Houten, Nederland.

Done at Brussels, 20.09.2004

For the Commission
Olli REHN
Member of the Commission